

Attachment VI: Summary of Safety and Effectiveness Information

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May 21, 1996

Synthes Sterile 7.0/7.3 mm Cannulated Screws are compared to Synthes 6.5 mm Cancellous Screws.

Synthes 7.0/7.3 mm Cannulated Screws are generally intended for fracture fixation of large bones and large bone fragments. Synthes 7.0/7.3 mm Cannulated Screws are available in multiple thread length configurations (16 mm, 32 mm or fully threaded). Both Screws feature reverse cutting flutes and cancellous threads. Additionally, the 7.3 mm Cannulated Screw features self-drilling/self-tapping flutes. Both screws are used in conjunction with a guide wire for precise placement in bone. Synthes 7.0/7.3 mm Cannulated Screws are manufactured from stainless steel. The 7.3 mm Cannulated Screw is also available in a titanium alloy.

Additionally, the Ace 6.5 mm Ti Cannulated Cancellous Screw System, the Richards 8.0 mm Cannulated Screw, and Zimmer Magna-Fx Cannulated Screw Fixation System are commercially available devices that are also similar to the 7.0/7.3 mm Cannulated Screws.

Synthes 7.0/7.3 mm Cannulated Screws will be provided sterile; Gamma radiation will be used to sterilize the device.

Based on mechanical testing, Synthes 7.0/7.3 mm Cannulated Screws are at least equivalent to Synthes 6.5 mm Cancellous Screws.